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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/483,434 01/14/00 MILLER

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EXAMINER

LEFFERS JR, G

ART UNIT

PAPER NUMBER

1636

DATE MAILED:

11/07/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/483,434

Applicant(s)
Miller, et al.

Examiner
Gerald G. Leffers Jr.

Group Art Unit
1636



☒ Responsive to communication(s) filed on Jul 24, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-14 is/are pending in the application.

Of the above, claim(s) 4, 5, 8, and 11-14 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-3, 6, 7, 9, and 10 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 6

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Receipt is acknowledged of applicants' response to the Restriction Requirement, filed 7/24/00, in which applicants elected with traverse Group I (claims 1-3 and 7). In response to the restriction requirement applicants argue that the Examiner has not met the burdensome search requirement for each of the groups and that the classification of groups I-III are the same. For Groups II, IV and VI this argument is not found to be persuasive because demonstration of either a different classification or a different non-patent literature search is all that is required to demonstrate a burdensome search on the part of the examiner. However, upon further review of the claims and the specification, Groups I, III and V have been rejoined because the non-patent literature required for each group is nearly co-extensive. The remaining groupings remain in place for the reasons of record (i.e. different and distinct inventions with different requirements for patent and non-patent searches). The requirement is still deemed proper and is therefore made FINAL.

Claims 4-5, 8 and 11-14 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 8, filed 7/24/00.

Receipt is also acknowledged of applicants Information Disclosure Statement filed 7/28/00. The signed and initialed PTO Form 1449 has been mailed along with this Action.

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Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3, 6-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: any step of actual transduction of the biologically active molecule or oligonucleotide into the interior of the cell.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Zanta et al (AH) or Baker et al (AA).

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Zanta et al teach in vitro gene delivery to hepatocytes with galactosylated polyethylenimine (Abstract; see entire document).

Baker et al teach the use of polyethylenimine as a simple, inexpensive and effective reagent for condensing and linking DNA to adenovirus for gene delivery to cells (Title; see entire reference). Baker et al teach that the PEI-adenovirus-DNA complex is contacted with target cells and the DNA incorporated into the cell via the adenoviral infectious route (Abstract).

Claims 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Al-Hakim et al (A) (see the entire patent).

Al-Hakim et al teach the construction and use of non-radioactive nucleic acid probes (Abstract). These probes feature an adduct of a basic macromolecule and biotin in which the macromolecule can be polyethylenimine (PEI) and in which the adduct can be cross-linked to a nucleic acid to form a non-radioactive nucleic acid hybridization probe (column 1, line 67 to column 2, line 68). The patent teaches that hybridization of the probe to the target nucleic acid sequence can be detected by an avidin-enzyme label complex which binds tightly to the biotinylated nucleic acid-PEI probe (column 3, lines 0-15).

Conclusion

No claims are allowed.

Certain papers related to this application may be submitted to Art Unit 1636 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official

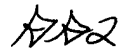
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Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald Leffers, Jr. whose telephone number is (703) 308-6232. The examiner can normally be reached on Monday through Friday, from about 9:00 AM to about 5:30 PM. A phone message left at this number will be responded to as soon as possible (usually no later than 24 hours after receipt by the examiner).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. George Elliott, can be reached on (703) 308-4003.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

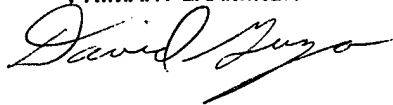


G. Leffers, Jr.

Patent Examiner

Art Unit 1636

DAVID GUZO
PRIMARY EXAMINER



November 6, 2000